PREFACE

This thesis is all about the understanding the process of registration of drugs in the global pharmaceutical market. It also describes about the requirements of various regions across the globe. The author is trying to spell out the exact similarities and differences between the regions.

Chapter 1 tells us about the general review and overall introduction to the subject.

Chapter 2 describes about the global pharmaceutical market. The entire global pharmaceutical market is classified into 3 categories i.e., Highly Regulated Market (HRM), Nearly Regulated Market (NRM) and Less Regulated Market (LRM).

Chapter 3 tells us about the regulatory requirements of HRM. In this chapter, author is trying to emphasize on the requirements of countries like USA, Europe, Japan, Canada & Australia.

Chapter 4 mentions the regulatory requirements of NRM. In this chapter, the author is trying to identify the requirements of regions like CEE, CIS, GCC, Brazil & South Africa.

Chapter 5 tells us about the regulatory requirements of LRM. In this chapter, the author is trying to state the requirements of different regions of ASEAN, Africa Latam, Middle East and Indian subcontinents.

Chapter 6 explains about the registration requirements as per ICH recommendations.

Chapter 7 tells us about the existing Indian regulations.

In chapter 8, the author is proposing a checklist for registration of a product in India based upon international norms.
Chapter 9 tells us about the requirements for the preparation of a dossier.

Chapter 10 describes about the conclusions.

All the references have been mentioned towards the end of this thesis.

The author is also trying to highlight that India being a major pharmaceutical exporting country does not have a firm guideline for marketing the product in its own territory.

The proposed registration checklist will be submitted to the DCGI for its effective implementation in letter and spirit.